
BY THE COMPTROLLER GENERAL

Report To The Congress

OF THE UNITED STATES

Federal Regulation Of Meat And Poultry Products--Increased Consumer Protection And Efficiencies Needed

The Department of Agriculture's Food Safety and Inspection Service establishes meat and poultry standards to protect the public against certain substances that may be injurious to health and to insure the products' nutritional quality. It also establishes labeling requirements to protect the public against misleading labels. The Service verifies that standards are met by testing finished products.

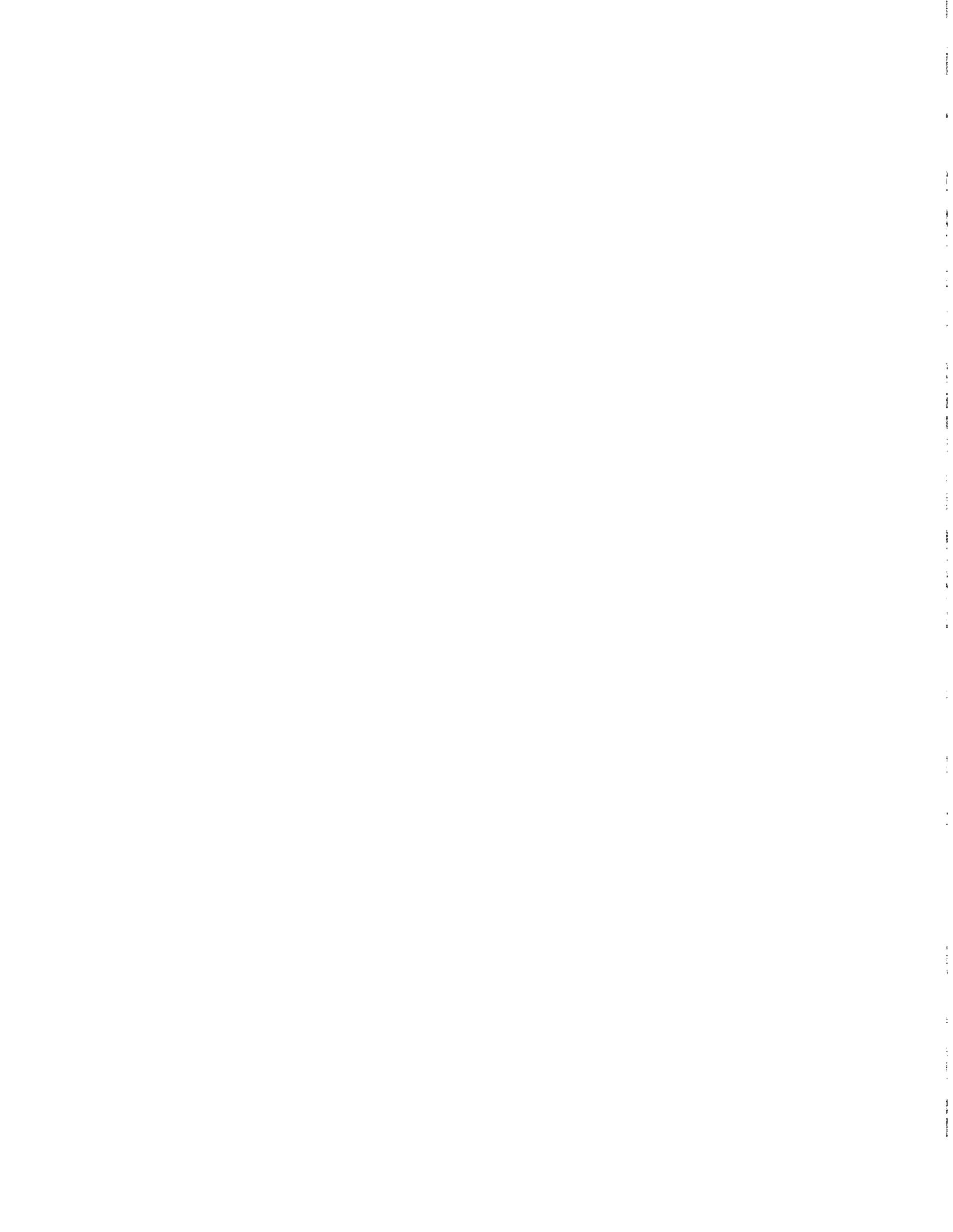
To better protect the public, the Service should establish specific standards and labeling requirements on certain processed poultry products as has been done for comparable processed meat products.

The Service could also be more efficient and effective in sampling processed meat products to determine that the products comply with established Federal standards.



GAO/RCED-83-68
MAY 4, 1983

025460/121263





COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON D.C. 20548

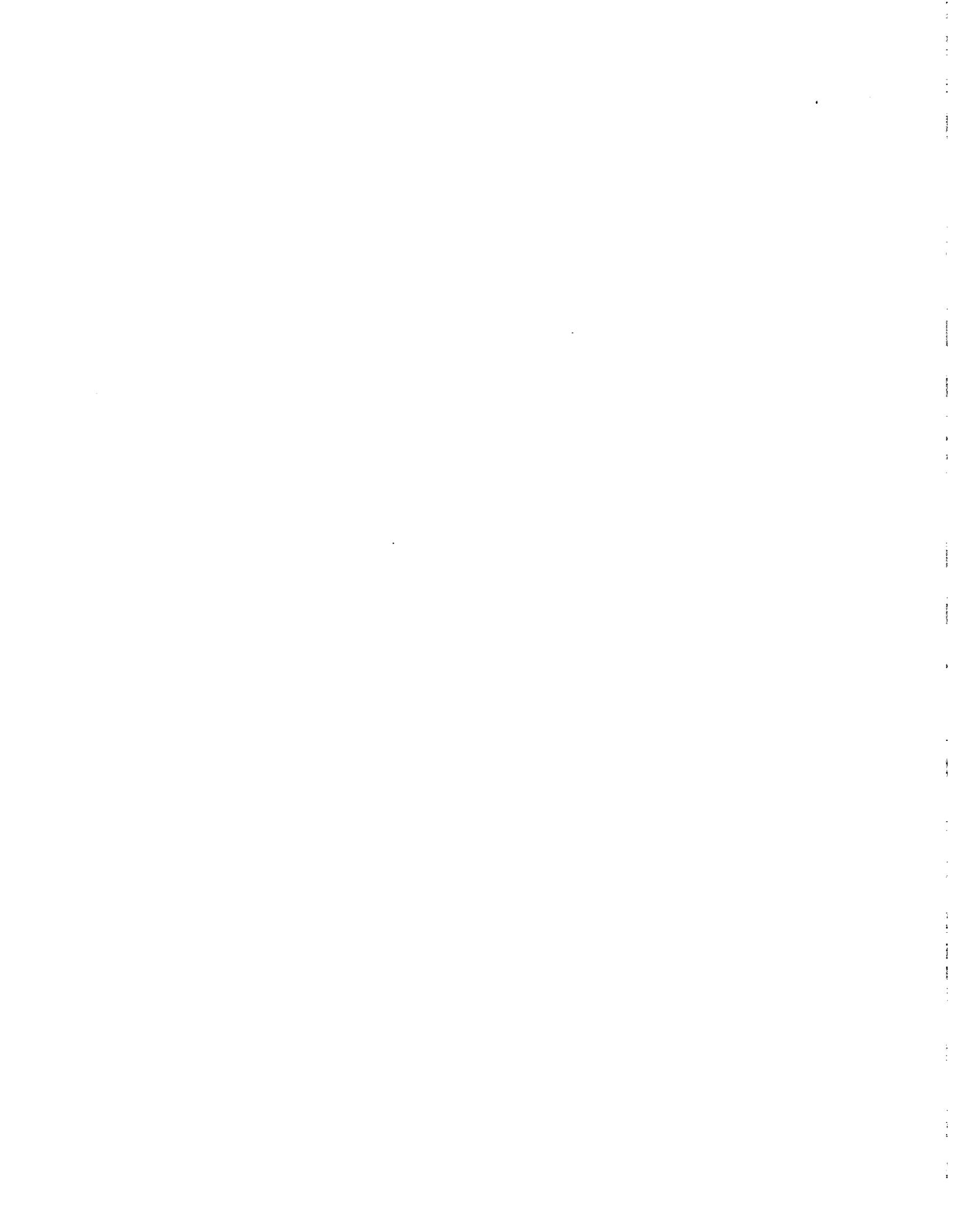
B-209696

To the President of the Senate and the
Speaker of the House of Representatives

This report discusses the Department of Agriculture's Food Safety and Inspection Service's regulation of processed meat and poultry products. We made the review because of the significant increase in the production of such products over the past decade. The Food Safety and Inspection Service inspected about 106.2 billion pounds of processed meat and poultry products in 1981 compared with about 69.5 billion pounds in 1971.

We are sending copies of this report to the Director, Office of Management and Budget; the Secretary of Agriculture; the House Committees on Agriculture, Appropriations, Budget, and Government Operations; and the Senate Committees on Appropriations, Budget, Governmental Affairs, and Agriculture, Nutrition, and Forestry.

Charles A. Bowser
Comptroller General
of the United States



D I G E S T

Products made with meat and poultry that is mechanically separated¹ contain some pulverized bone, bone marrow, and certain minerals that may be harmful. Consequently, to protect the public, the Food Safety and Inspection Service of the Department of Agriculture established specific standards in 1974 and labeling requirements in 1978 on mechanically separated meat (MSM).

Although a Department of Agriculture study has shown that similar health and safety problems exist for products made with mechanically separated poultry (MSP), the Service has not established specific standards and labeling requirements for these products. It has not because it wanted to first resolve concerns about MSM. Secondly, the Service said that products made with MSP were already somewhat covered by regulations which limited their bone content to 1 percent.

Since MSM standards and labeling requirements were established, controversy has continued--including court cases--among consumer protection organizations, producers, and the Service over the appropriateness and adequacy of the MSM standards and labeling requirements in protecting the public against adulterated products and misleading product labels. Because of this controversy, the Service has periodically adjusted the MSM standards and labeling requirements--the latest change being in July 1982. It does not plan to establish specific standards and labeling requirements on MSP or products made with MSP until the MSM controversy--including resolution of the latest court case--is resolved. (See pp. 6 to 11.)

¹ Mechanically separated refers to the separating and removing, by machine, of skeletal muscle from meat and poultry bones after most of the meat and poultry has been removed by hand.

Because of the significant increase in production of new types of processed meat and poultry products over the past decade, GAO made its review to determine whether (1) standards have been developed to help assure consumers of the uniformity and consistency of products, (2) products are properly labeled, and (3) sampling procedures are efficient and effective.

NEED FOR SPECIFIC STANDARDS
AND LABELING REQUIREMENTS

A major purpose of the Poultry Products Inspection Act of 1957 is to prevent the sale of adulterated poultry products, which it defines as any product that "bears or contains any poisonous or deleterious substance which may render it injurious to health." Products produced with MSP from fowl (mature female chickens) contain fluoride which can, if excessive amounts are consumed by children while their permanent teeth are being formed, cause permanent mottling (spotting of enamel) of their teeth. GAO believes that, because of this potential problem, the Service needs to establish standards for using mechanically separated fowl in baby foods. The Service has prohibited products made with MSM in baby foods because of MSM's fluoride content. (See pp. 11 and 12.)

Because MSM is different from hand-separated meat in that it, among other things, contains higher amounts of calcium and cholesterol, the Service established product standards and labeling requirements to prevent MSM products with misleading labels from being sold to consumers. The Service, however, has not taken similar action to protect consumers of products produced with MSP. Given the same quantities of MSM and MSP, MSM contains more calcium and cholesterol than MSP. However, products produced with MSP contain higher amounts of calcium and cholesterol than products produced with hand-separated poultry. Without product standards and labeling requirements, consumers cannot differentiate between products made with MSP and hand-separated poultry and are not being afforded the same protection against misleading labels as consumers of products made with MSM. (See pp. 12 to 14.)

National Broiler Council members told GAO that the Council was against further regulation of the poultry industry and that increased levels of fluoride, calcium, and cholesterol associated with MSP have not proven to be harmful to the general public. (See p. 14.)

Although poultry producers enjoy an economic and competitive advantage over meat producers because poultry products generally cost less to produce, differences in labeling requirements give poultry producers an even greater economic and competitive advantage over meat producers. Poultry firms use the relatively inexpensive MSP extensively in products, while meat firms, because of the specific labeling requirements, have made limited use of MSM. About 330 million pounds of MSP products were produced in 1979, while only 2.3 million pounds of MSM products were produced compared with a potential production of 351.7 million pounds. (See pp. 15 and 16.)

Concerning a related issue, the Service also established standards on the maximum fat and added water that cooked meat sausage products can contain to assure the products' nutritional quality, consistency, and uniformity. The Service samples and tests these products to determine compliance. But again, the Service has not established similar standards on cooked poultry sausage products to assure their nutritional quality, uniformity, and consistency. The Service did propose cooked poultry sausage standards in 1976, but higher priority issues at that time, such as resolving the carcinogen controversy over nitrites, prevented the adoption of these standards. (See pp. 16 to 18.)

GAO recommendations

GAO recommends that, to help assure consumers of wholesome, properly labeled, and nutritious products, the Secretary of Agriculture direct the Service to establish specific standards on MSP and labeling requirements on products made with MSP, as has been done for MSM and products made with MSM. The Department agreed and said that the Service intends to develop a proposed regulation on MSP after the latest court case is resolved. (See pp. 18 and 19.)

GAO also recommends that the Secretary direct the Service to establish standards on the maximum fat and added water that cooked poultry sausages can contain and sampling and testing procedures to determine compliance with the standards. The Department said that proposed standards were under active consideration. (See pp. 18 and 19.)

MEAT PRODUCT SAMPLING COULD BE MORE
EFFICIENT AND EFFECTIVE

To assure product compliance, the Service takes three types of samples on processed meat products. These are referred to by the Service as verification, split, and regulatory samples. Verification samples are taken to check on the plants' quality control systems. Split samples are taken to check on the plants' accredited laboratories'² quality and integrity. Regulatory samples are taken by either the Service or accredited laboratories to determine product compliance with Federal standards.

Verification samples

The Service does not consider the effectiveness of the quality control systems nor the plants' compliance histories in determining the frequency for verification samples it takes. GAO reviewed the adequacy of 12 plants' quality control systems for fat, added water, and added substance over a 1- to 2-year period and found that 11 of the systems were effective in determining compliance with Service standards. The Service could reduce the frequency for samples it takes on products produced under these 11 systems without any significant loss of assurance that the products will remain in compliance. About 185 systems operate nationwide. (See pp. 20 to 24.)

² Accredited laboratories are non-Federal laboratories that have been approved by the Service to make tests of products to determine product compliance with product standards. Usually the laboratories are owned and operated by individual processing plants.

Split samples

GAO's review of eight accredited laboratories showed that the Service had developed sufficient compliance histories on seven to enable it to reduce the number of split samples it takes on these laboratories. Split-sample results on the eighth accredited laboratory were not available for a sufficient period to judge its compliance history. About 200 accredited laboratories operate nationwide. (See pp. 24 to 26.)

The Service had not followed its procedures to investigate and resolve major discrepancies between its own laboratory results and those of accredited laboratories on split samples. GAO found 94 major discrepancies between the results of tests made by a Service laboratory and the seven accredited laboratories noted above over a 2-year period that had not been investigated and resolved. As a result, the Service had no way of knowing which laboratory used the proper handling and/or analytical procedures in determining sample results. (See pp. 26 and 27.)

Regulatory samples

Some out-of-compliance products had entered the marketplace because plant inspectors had not always received regulatory-sample results in a timely manner. GAO found that inspectors received test results an average of 17 days after they had sent the samples to the Service field laboratory for testing. Since some of the plants shipped products in 3 days or less, those products found to be out of compliance may have already been marketed. As a result, consumers may not have received what they paid for.

This problem did not exist to the same degree when accredited laboratories were used. This was because results from accredited laboratories were generally known to the inspectors within a day or two. Although the Service's inspectors have other monitoring techniques available to them to check on plants producing out-of-compliance products, the Service needs to encourage plants to use nearby accredited laboratories. (See pp. 27 to 29.)

GAO recommendations

GAO recommends that, for more efficient and effective sampling of processed meat products for compliance with established Service standards, the Secretary direct the Service to:

- Reduce verification sampling at plants with quality control systems that have good histories of compliance. The Service should also reduce split sampling at plants that have accredited laboratories with good histories of compliance.
- Enforce its procedures on investigating and resolving major discrepancies on split-sample results between Service field laboratories and accredited laboratories.
- Provide inspectors with timely sample results on product compliance by reducing the backlog of samples at Service field laboratories and encouraging plants to use nearby accredited laboratories. (See pp. 30 and 31.)

AGENCY COMMENTS AND GAO EVALUATION

The Department agreed with all but one of GAO's recommendations. (See app. I.) It said that GAO's recommendation concerning out-of-compliance products reaching the marketplace was unnecessary based on the findings presented in the report. According to the Department, the recommendation misrepresented the record of consumer protection the Service has achieved. GAO did not intend to misrepresent the Service's record on consumer protection and, in response to the Department's concern, clarified the recommendation to emphasize the need for more timely sample results--a need that is clearly demonstrated in the report. (See pp. 31 to 33.)

C o n t e n t s

		<u>Page</u>
DIGEST		i
CHAPTER		
1	INTRODUCTION	1
	Processed products inspection requirements	1
	FSIS' organization	2
	Objectives, scope, and methodology	3
2	SPECIFIC STANDARDS AND LABELING REQUIREMENTS ARE NEEDED ON PROCESSED POULTRY PRODUCTS	6
	Products made with MSP may be adulterated and their labels misleading	8
	Standards are needed on cooked poultry sausages	16
	Conclusions	18
	Recommendations	18
	Agency comments and our evaluation	19
3	MEAT PRODUCT SAMPLING COULD BE MORE EFFICIENT AND EFFECTIVE	20
	Verification samples should be reduced	20
	Split samples should be reduced	24
	More timely sample results on product compliance needed	27
	Conclusions	30
	Recommendations	30
	Agency comments and our evaluation	31
APPENDIX		
I	Letter dated January 17, 1983, from Administrator, Food Safety and Inspection Service, Department of Agriculture	34

ABBREVIATIONS

FSIS	Food Safety and Inspection Service
GAO	General Accounting Office
MPIO	Meat and Poultry Inspection Operations
MPITS	Meat and Poultry Inspection Technical Services
MSM	mechanically separated meat
MSP	mechanically separated poultry
USDA	U.S. Department of Agriculture



CHAPTER 1

INTRODUCTION

The Federal Meat Inspection Act, as amended (21 U.S.C. 601 et seq.), and the Poultry Products Inspection Act, as amended (21 U.S.C. 451 et seq.), require the Secretary of Agriculture, through the Food Safety and Inspection Service (FSIS), to inspect the slaughter of livestock and poultry and the processing of meat and poultry products shipped interstate or to foreign markets. The primary objective of these laws is to help assure that meat and poultry products are wholesome, unadulterated, and properly labeled and packaged.

FSIS carries out its inspection activities under four general categories: (1) ante mortem--examining animal/poultry health and fitness before slaughter, (2) post mortem--inspecting carcasses after slaughter but before processing to establish their wholesomeness for human consumption, (3) sanitation--supervising sanitary conditions at both slaughter and processing plants, and (4) product processing--inspecting the boning and cutting, curing and smoking, and canning operations, and the further processing of meat and poultry products into finished products. This report deals with the product processing inspection activities of meat and poultry.

PROCESSED PRODUCTS INSPECTION REQUIREMENTS

Although the meat and poultry acts authorize inspecting all processed meat and poultry products shipped interstate or to foreign markets, they do not prescribe a specific method of inspection. Products are subject to inspection as often as deemed necessary. To comply with the acts, FSIS has established (1) controls over the entry of carcasses and other materials into processing plants, (2) guidelines on the manufacturing processes and procedures used in formulating processed products, (3) standards on the minimum amount of meat and poultry and maximum amounts of fat, added water, or other ingredients that processed meat products can contain, and (4) guidelines on periodic sampling of products to verify compliance with requirements and standards.

FSIS has also established programs allowing processing plants to implement partial or total quality control systems voluntarily. Quality control systems reduce the need for continuous FSIS inspections. Under a quality control system, plant management is responsible for producing products that comply with all regulatory requirements and FSIS inspectors monitor

the system to determine if it is effective. Partial quality control systems monitor processing operations for a specific operation, such as amounts of fat and water in cooked meat sausage products, whereas total quality control systems control the entire food production process. FSIS publications state that quality control systems could help FSIS to carry out its processing inspection responsibilities in a more efficient way.

Production of processed products has increased significantly

Over the past decade, the amount of processed meat and poultry products produced and the number of plants producing these products have increased significantly. Due to changing lifestyles, Americans have been purchasing greater amounts of convenience foods and spending less time preparing meals.

The increase in processed meat and poultry products has increased FSIS' inspection activities for these products. In 1971 FSIS inspected about 69.5 billion pounds of processed meat and poultry products at about 4,300 plants; in 1981 FSIS inspected about 106.2 billion pounds at about 6,800 plants, an increase of about 53 percent and 58 percent, respectively.¹ Direct inspection costs increased from \$28 million to about \$76 million over this period.

FSIS' ORGANIZATION

Three organizations within FSIS are responsible for the processed meat and poultry inspection program. Meat and Poultry Inspection Operations (MPIO) is responsible for applying uniform national inspection standards and for inspecting meat and poultry products. As of February 1983, MPIO included a headquarters office, 5 regional offices, and 27 area offices. Each area office is divided into several circuits, with a circuit supervisor responsible for overseeing the inspection activities in a number of plants.

MPIO inspection staff size at each processing plant depends on the processing volume and the products being processed. It can range from one part-time inspector to several full-time inspectors. The inspectors determine that (1) the meat and poultry products entering the plants are wholesome, (2) approved

¹ These pounds reflect some multiple counting of processed products because of required inspections at various points during product processing.

procedures are followed, (3) only wholesome and approved ingredients are used, (4) finished products are properly packaged, marked, labeled, and meet the appropriate Federal standards, and (5) condemned products do not leave the plant.

FSIS' Meat and Poultry Inspection Technical Services (MPITS) is responsible for a broad range of functions that support MPIO. Two primary functions are to develop product standards, such as the amount of fat and added water that products can contain, and to develop labeling policies and carry out label approval functions. Product standards specify the meat, poultry, and other ingredients of meat and poultry products. FSIS reviews proposed product labels to help assure that they are truthful and not misleading and that the ingredients used conform to the product standards.

FSIS' Science organization provides analytical support and scientific guidance to MPIO and MPITS through (1) laboratory analyses of products to determine product compliance with product standards and (2) approval and review of accredited laboratories. Accredited laboratories are non-Federal laboratories that have been approved by FSIS to make tests of products to determine product compliance with product standards. Usually accredited laboratories are owned and operated by individual plants. Plant laboratories request accreditation from FSIS because of the convenience of testing their own products rather than shipping sampled products to an FSIS field laboratory. The Science organization has three Federal field service laboratories and contracts with three State laboratories to analyze products for compliance.

OBJECTIVES, SCOPE, AND METHODOLOGY

Because of the significant increase in the production of new types of processed meat and poultry products over the last decade, we reviewed FSIS' processed products inspection activities to determine whether (1) product standards have been developed to help assure consumers of products' uniformity and consistency, (2) product labels are accurate, truthful, and not misleading, and (3) sampling procedures used to measure product compliance are efficient and effective.

We hired a consultant, Dr. Robert N. Terrell, Associate Professor, Department of Animal Science, Texas A&M University, to assist us in comparing differences in the standards and labeling policies FSIS imposes on meat and poultry products. This report was reviewed by our permanent medical advisor.

We made the review in accordance with generally accepted government auditing standards. We reviewed legislation, regulations, and instructions governing FSIS processing inspection activities. Our examination of records and our interviews with FSIS headquarters, regional, and area office officials and processing inspectors covered various aspects of the processing inspection activities, including product sampling, labeling, and standards; implementing and monitoring partial and total quality control systems; and general inspection activities.

Our review was conducted at FSIS headquarters, Washington, D.C.; at its North Central Regional Office, Des Moines, Iowa, and Southwest Regional Office, Dallas, Texas; and at its Ames, Iowa, Topeka, Kansas, and Jefferson City, Missouri, area offices. We also visited the Program Review Branch in Lawrence, Kansas, which is responsible for making in-plant compliance reviews; an FSIS field service laboratory at St. Louis, Missouri; and 15 processing plants in Iowa and Missouri. At the processing plants, assisted by FSIS processing inspectors and, in some cases, circuit supervisors, we examined sampling results to determine product compliance with standards, plant formulas and processing procedures, and labels. We also observed the various manufacturing processes and procedures used in formulating processed products, interviewed plant personnel, and examined plant records relating to the plants' partial quality control systems and product formulations and sampling procedures. We made our plant visits from February to April 1982.

We met with the National Meat Association, the National Broiler Council (a poultry association), and the Community Nutrition Institute (a consumer protection organization) to ascertain their views on the need for standards on meat and poultry products. We also coordinated our work with the U.S. Department of Agriculture's (USDA's) Office of Inspector General and identified and reviewed relevant Inspector General audit reports.

Our review covered meat products that are further processed (products that need additional processing beyond the cutting, boning, and slicing operations) and for which standards have been established on fat, added water, and added substance.

Sausage; smoked, dried, and cooked meats; and canned products are the three categories of processed meat products for which standards on fat, added water, and/or added substance have been established. These three categories represent 41 product types. We reviewed six of these product types, including frankfurters, bologna, and fresh pork from the sausage category; nonwater-added and water-added hams from the smoked, dried, and

cooked category; and canned hams from the canned category. These six items were selected because of their consumer popularity. Collectively, these 6 items represent over 40 percent of the 1981 production for all 41 product types produced. We also reviewed further-processed poultry products, such as chicken frankfurters and turkey frankfurters and bologna, that are similar to the meat products reviewed.

We specifically selected plants in Iowa and Missouri because of their large volume of further-processed products and because we wanted to provide some coverage of plants in two of FSIS' five meat and poultry inspection organizations' regions. In 1981 Iowa and Missouri accounted for about 600 million pounds, or about 12 percent of the nationwide production, of the six items we reviewed.

We selected 15 processing plants considering size, location, volume, and types of further-processed products and plants with partial quality control systems and those without. Collectively, the plants visited produced about 66 percent of the further-processed meat products reviewed in the two States and about 8 percent of the national total. Production figures on further-processed poultry products could not be summarized because FSIS does not maintain production data on specific further-processed poultry products. Of the plants visited, 1 processed only poultry products, 3 processed both meat and poultry products, and 11 processed only meat products.

The FSIS and plant activities reviewed do not represent a random sample nor are they statistically representative, and therefore our findings in chapter 3 cannot be projected for all plants. However, the findings discussed in chapter 2 are national in scope in that they represent an FSIS policy decision and are uniformly applied to all poultry producers throughout the country.

CHAPTER 2

SPECIFIC STANDARDS AND LABELING REQUIREMENTS

ARE NEEDED ON PROCESSED POULTRY PRODUCTS

FSIS has established standards and labeling requirements for processed meat and poultry products. These include the minimum amount of meat and poultry that these products can contain and ingredient labeling statements on product packages. FSIS has also established (1) specific standards and labeling requirements on processed meat products made with mechanically separated meat (MSM)¹ ingredients to protect the public against adulterated products (products that bear or contain any poisonous or deleterious substance that may render it injurious to health) and misleading product labels and (2) additional standards on cooked meat sausage products to assure the public of the nutritional quality of these products. However, FSIS has not established specific standards and labeling requirements on processed poultry products made with mechanically separated poultry (MSP) ingredients or additional standards on cooked poultry sausage products.

Because MSM and MSP contain some pulverized bone, bone marrow, and certain minerals, processed meat and poultry products made with MSM and MSP contain higher levels of fluoride, calcium, and cholesterol than processed meat and poultry products made from traditional hand-separated meat and poultry. The presence of these substances caused USDA to establish specific standards and labeling requirements on products made with MSM; however, it has not established specific standards and labeling requirements on products made with MSP. As a result, products made with MSP may be adulterated and their labels misleading.

To protect the public against adulterated products, USDA has prohibited MSM in baby foods because the increased amount of fluoride in MSM is a potential problem for children. To protect the public against possible misbranded products because of misleading labels, USDA has established specific standards and labeling requirements on MSM to (1) aid consumers in differentiating between products containing MSM and traditional

¹ Current FSIS regulations define this ingredient by the name of mechanically separated (species) or MS(S); however, to eliminate confusion of terms, this report refers to this ingredient as mechanically separated meat (MSM).

hand-separated meat, (2) restrict the amount of MSM that processed meat products can contain to minimize the effects of increased levels of calcium and cholesterol, and (3) alert consumers on calcium-restricted diets.

Although products made with MSP have been marketed since the mid-1960's, about 10 years before products made with MSM, the FSIS Administrator said that FSIS decided to establish appropriate standards and labeling requirements on MSM products before MSP products. He said that in the early 1970's increased public awareness on nutrition and health aspects of food products and the development of food labeling guidelines resulted in considerable controversy over MSM. The Administrator said that at the time meat processors had the technology to produce MSM products, FSIS took the position that it should establish appropriate standards on MSM before it was commercially produced. He also said that products made with MSP were already somewhat covered by regulations established in 1969. (See p. 9.)

The MSM standards have been a source of controversy among consumer protection organizations, producers, and FSIS--including court cases over the appropriateness of the MSM standards--since they were published in 1974. Because of this controversy, FSIS, in 1978, established labeling requirements on finished products made with MSM and has continued to periodically amend the MSM standards and labeling requirements. The latest amendments took effect on July 29, 1982. The FSIS Administrator said that FSIS does not plan to make a decision on the need to establish specific standards and labeling requirements on products made with MSP until the MSM controversy--including resolution of the latest court case--is resolved.

USDA has also established product standards limiting the amount of fat and added water in cooked meat sausage products, such as beef and pork frankfurters and bologna, to assure that these products meet a minimum level of nutritional quality and that they are produced in a uniform and consistent manner. However, for cooked poultry sausage products, such as chicken frankfurters and turkey frankfurters and bologna, USDA has not established similar standards. FSIS' Deputy Administrator, MPITS, said that although FSIS proposed fat and added-water standards on cooked poultry sausage products in 1976, they were not adopted because of higher priority issues at that time, such as resolving the carcinogen controversy over nitrites. He said that FSIS was considering proposing standards on cooked poultry sausage products.

PRODUCTS MADE WITH MSP MAY BE ADULTERATED
AND THEIR LABELS MISLEADING

FSIS established specific product standards and labeling requirements for MSM, but has yet to for MSP, even though the health and safety aspects of using MSP are similar to those of using MSM. Also, production of products made with MSP and their consumption has been far greater than that of products made with MSM. In 1979² about 330 million pounds of products made with MSP were produced and consumed compared with 2.3 million pounds of products made with MSM. The lack of MSP standards and labeling requirements is providing an economic and competitive advantage to the poultry processing producers over the meat processing producers.

Background on mechanically
separated product

MSM or MSP is a finely pulverized product resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle. The bones remaining after most of the skeletal muscle of meat and poultry has been removed by hand-deboning techniques are used to produce this product. These bones are broken up and pushed under high pressure through equipment with openings that separate the bones from the attached tissues. The remaining meat or poultry product consists of soft skeletal muscle tissue and a small amount of powdered bone. This product differs from traditional meat and poultry products in that it is highly pulverized; has a spread-like consistency; and in addition to muscle tissue, contains bone, bone marrow, and minerals such as fluoride and calcium.

Processed meat products that can contain MSM include beef patties, beef and pork frankfurters and bologna, fresh pork sausage, luncheon meats, chili con carne, tamales, meat stew, spaghetti with meat balls and sauce, and chop suey vegetables with meat. Processed poultry products that can contain MSP include baby foods, chicken frankfurters, turkey frankfurters and bologna, poultry rolls, and various other formulated poultry products.

² Latest data available.

Regulatory efforts have
been on MSM and not MSP

Products made with MSP were first sold commercially in the United States in the mid-1960's. In 1969 USDA published regulations on the labeling of boneless poultry which included products made with MSP; these regulations have not been amended and are still in effect. The boneless poultry regulations limit the bone residue in boneless poultry to 1 percent, and based on these regulations, USDA only requires the product's label ingredient statement to state the species used, such as chicken or turkey.

Most of the controversy about using a mechanically separated product and the ensuing product regulations on product standards and labeling requirements have centered on MSM. According to our consultant and the FSIS Administrator, this is probably the result of increased public awareness on nutrition and health aspects of food products and the development of nutrition food labeling guidelines at about the time MSM products began being sold commercially.

USDA approved the use of MSM in November 1974 and issued a bulletin stating that processed products made with MSM could be produced and sold in the United States under certain conditions. These conditions included labeling the product as mechanically deboned and stating the species, such as "mechanically deboned beef"; identifying the species name on the ingredient statement; and making producers develop and obtain an approved quality control system on the equipment and processing techniques used. In an April 1976 interim regulation, USDA further modified the 1974 conditions by providing a specific definition for MSM, which limited MSM to 20 percent of the meat portion of the processed product, and by prohibiting certain processed meat products from being made with MSM. Specifically, USDA has prohibited MSM in baby foods because the increased amount of fluoride in MSM is a potential problem for children.

As a result of the 1976 interim regulation, the Community Nutrition Institute and others petitioned the U.S. District Court, District of Columbia,³ charging, among other things, that the MSM regulations would permit the sale of adulterated and misbranded meat products, contrary to the provisions of the

³ Community Nutrition Institute et al. v. Earl L. Butz, Secretary of Agriculture, 420 F. Supp. 751 (U.S. D.C. D.C. 1976).

Federal Meat Inspection Act. The court, on September 10, 1976, entered a preliminary injunction to prohibit the interim regulation from taking further effect, thus preventing the use of MSM in processed meat products. In doing so, the court held that the Secretary would be unlikely to prevail in a trial on the merits of the case because the Secretary had not adequately considered the health aspects of the bone particles in MSM, which might make it an adulterated product under the Federal Meat Inspection Act.

Because the court's action prevented the interim regulation from taking further effect, production of MSM stopped. USDA studied the health and safety aspects of MSM that the court said were lacking. In 1977 USDA proposed new regulations that, after comment and public hearing, became effective in 1978. USDA rejected two petitions from a meat association to modify the 1978 regulations but finally revised them effective July 29, 1982. These revised standards and labeling requirements, which included many of the requirements established in 1978, included:

- Stating on the ingredient label mechanically separated (name of species).
- Declaring the calcium content per serving (under certain circumstances) on the labels of finished products.
- Limiting MSM to not more than 3/4 of 1 percent calcium as a measure of bone content and restricting bone particle size.
- Limiting to 20 percent the amount of MSM in the meat portion of the finished product.
- Prohibiting MSM use in infant, junior, or toddler foods (referred to herein as baby foods).
- Requiring producers to have an approved quality control system to commercially produce MSM.

On July 20, 1982, the Community Nutrition Institute and three other consumer protection organizations filed a complaint in the U.S. District Court, District of Columbia, against USDA. They charged, among other things, that the then upcoming July 29, 1982, final rule on MSM regulations would permit the sale of adulterated and misbranded meat products, contrary to the provisions of the Federal Meat Inspection Act. They charged that MSM products would be adulterated because MSM product

labels would conceal the fact that the products were not ordinary meat products and that their contents may have serious health implications for significant segments of the population. They charged that MSM products would be misbranded because their labeling would fail to inform consumers that the products contained a unique and unexpected substance consisting of tissue, bone, and bone marrow.

On December 1, 1982, the court entered judgment for USDA in this case (Civil Action No. 82-2009), holding the final rule on labeling and use of MSM to be lawful under the Federal Meat Inspection Act. The court's judgment is based on a lengthy opinion that thoroughly considered the issues the Community Nutrition Institute raised and the evidence USDA submitted supporting its regulations. The court found the regulations in the final rule to be reasonable, rationally based, and supported by the evidence. On December 14, 1982, the Community Nutrition Institute filed a notice of appeal. As of April 4, 1983, the appeal was pending.

Some poultry products produced
with MSP may be adulterated

Products produced from MSM contain various amounts of fluoride that may result in a potential problem for children while their permanent teeth are being formed. Because of this problem and the need to protect the public against adulteration, products produced with MSM are prohibited in baby foods. Although this same potential problem can exist in products made with MSP, MSP is allowed in baby foods. A 1979 USDA health and safety study on MSP stated that intakes of fluoride from mechanically separated fowl could be excessive.

One of the main purposes of the meat and poultry inspection acts was to prevent the sale of adulterated meat and poultry products. Both acts define adulterated as a product that "bears or contains any poisonous or deleterious substance which may render it injurious to health."

After the U.S. District Court said in 1976 that MSM might be considered adulterated because USDA did not adequately consider the health aspects of its bone content, USDA assembled a panel to study the health effects of MSM. As part of that study, the panel reviewed the health and safety aspects of fluoride contained in MSM. In the study, issued in 1977, the panel concluded that the intake of fluoride in infants could have adverse effects because excessive intake of fluoride when teeth are being formed could cause permanent mottling (spotting of enamel). The panel also concluded that because no long-term

data existed on the fluoride content of MSM and the fluoride content of MSM may vary by locality, MSM should not be used in baby foods. The panel said that this conclusion was based on the lack of information rather than evidence of a health hazard and should be subject to further evaluation as data is gathered. Based on the panel's conclusions, USDA decided that MSM should be excluded from baby foods. In November 1982 the Administrator said FSIS has made no further evaluations on MSM's fluoride content.

USDA also issued a health study in 1979 on MSP's health and safety aspects. As part of that study, USDA reviewed the health and safety aspects of fluoride contained in MSP. The study concluded that, except for fowl (mature female chickens), there were no health hazards associated with MSP. The study stated that the fluoride content of fowl bones was high and MSP made with fowl had a high fluoride content like MSM. The study recommended that mechanically separated fowl should be prohibited in baby foods because of the lack of information on fluoride intakes of infants in high-fluoride areas and USDA's prior determination of not permitting MSM in baby foods.

In July 1982, an FSIS food technologist told us that mechanically separated fowl was being used by two of the three baby food producers she contacted as a result of our inquiry. The Labeling Branch Chief of FSIS' Standards and Labeling Division said that since no regulations exist that require identifying the specific poultry used in products made with MSP, he does not know how much mechanically separated fowl is being used in baby food products. He said it could be widespread.

Specific product standards and labeling requirements needed on MSP

USDA has established standards and labeling requirements on MSM to aid consumers in differentiating between products made with MSM and traditional hand-separated meat. USDA also restricts the amount of MSM that can be used in the meat portion of processed meat products to 20 percent because of the higher calcium and cholesterol content of MSM. In addition, USDA has established calcium content labeling requirements for finished products to alert consumers on calcium-restricted diets to the calcium content, where appropriate.

Given the same quantities of MSM and MSP, MSM contains more calcium and cholesterol than MSP. However, products produced with MSP contain higher amounts of calcium and cholesterol than

products produced with hand-separated poultry. However, USDA has not established specific standards and labeling requirements on these products. As a result, consumers cannot differentiate between products made with MSP and hand-separated poultry and are not informed of the higher amounts of calcium and cholesterol.

In its latest amendments on standards and labeling requirements for MSM, which were published in the June 29, 1982, Federal Register and became effective July 29, 1982, USDA said that MSM should be separately defined, standardized, and identified by a name that adequately differentiates it from traditional meat. USDA said that MSM differed from traditional meat because of its consistency; muscle tissue structure; and presence of bone, bone marrow, and certain minerals. USDA said further that MSM also must be identified on ingredient labels to meet USDA's obligation of assuring that the public is apprised of MSM's presence in food products. USDA also said that the ingredient label is where consumers should look if they are interested in a food's content, seeking out or avoiding particular ingredients, or distinguishing between brands of meat products.

USDA has not taken similar action for products made with MSP even though the products' contents are similar. Currently, MSP is considered as boneless poultry and the ingredient label on products made with MSP states simply chicken or turkey.

Because MSM has a higher amount of calcium than traditional hand-separated meat, USDA restricted to 20 percent the amount of MSM that can be used in the meat portion of products made with MSM to minimize the effect of increased calcium. In addition, USDA concluded that persons on calcium-restricted diets should be made aware of the higher amounts of calcium in MSM. As a result, USDA required labels on meat products made with MSM to state the calcium content as part of nutritional labeling or, if nutritional labeling is not used, as a statement in conjunction with the label ingredient statement that the product contributes a certain percentage of the recommended daily allowance of calcium.

Although MSP also contains bone and a higher amount of calcium than hand-separated poultry, USDA has not established calcium labeling requirements on products produced with MSP nor has it limited the amount of MSP that can be included in poultry products. One hundred percent of the poultry used can be produced with MSP. Of the four plants in our review that produced poultry products, three used 100-percent MSP in the products we reviewed. (The one plant that did not use 100-percent MSP used

only hand-separated poultry.) According to the USDA health study on MSP, the calcium levels of the products using 100-percent MSP can be up to twice as high as those for products made with MSM because MSM is limited to 20 percent.

Consumers are not being adequately informed of this and can be misled. For example, if a person on a calcium-restricted diet were to check the label for frankfurters, the calcium content of beef frankfurters made with mechanically separated beef would be shown. However, chicken frankfurters made with mechanically separated chicken do not have a calcium statement. This person may choose the chicken frankfurters thinking they contain a lower calcium level when the product may contain up to twice as much calcium.

The current MSM standards restrict MSM use to 20 percent of the meat portion of products made with MSM. The restriction was established because MSM has a higher calcium content than products made without MSM. USDA also said that as long as MSM is restricted to 20 percent of the meat portion, products made with MSM will also only be slightly higher in cholesterol than traditional meat products and will not lead to any appreciable increases in dietary cholesterol intakes.

The USDA study on the effects of MSP concluded that the cholesterol content of MSP was about double that of hand-separated poultry flesh and about the same or slightly higher than poultry skin. Although the study stated that daily increases in cholesterol consumption from MSP use would be negligible on a per capita basis, it concluded that because persons who need to watch their cholesterol intake often replace meat with poultry, foods containing MSP should be specifically labeled to show its presence. The study stated that although the cholesterol consumption from MSP would not pose a health problem for the general public, it could pose problems for persons who have a hereditary condition known as "familial Type II hypercholesterolemia" (excess cholesterol in the blood) and who must control their cholesterol intake.

We met with members of the National Broiler Council to get their views on the need for specific standards on MSP and labeling requirements on products made with MSP. They said the Council was against the further regulation of the poultry industry. The members said that the increased levels of fluoride, calcium, and cholesterol associated with MSP have not proven to be harmful to the general public. The Council did not believe that specific standards and labeling requirements should be required on products that may be harmful to only a small percentage of the public.

MSP producers have an economic and competitive advantage over MSM producers

Poultry producers enjoy an economic and competitive advantage over meat producers because poultry products generally cost less to produce. However, poultry producers enjoy an even greater economic and competitive advantage because they can use the relatively inexpensive MSP extensively in products while meat producers, because of specific standards and labeling requirements, have made limited use of MSM. According to a USDA June 1982 regulatory impact analysis on MSM regulations, the cost of producing MSM is less than the cost of producing hand-separated meat products. The impact analysis stated that in 1979 the average cost of producing MSM was between 30 and 40 cents a pound. According to USDA, the same costs in 1979 for traditional hand-separated meat ranged between 42 cents and \$1.13 a pound for beef and between 22 and 81 cents a pound for pork.⁴ In 1979 the average cost to produce MSP was 23 cents a pound.

Also contributing to MSP's advantage is the 20-percent limit on the MSM content in meat products. The amount of MSP in poultry products is not limited. The costs associated with producing products containing MSM are higher than the costs to produce similar products made with MSP because 80 percent of the meat product must come from the higher priced hand-separated meat.

Another factor that might add to MSP's advantage is FSIS' requirement that to receive label approval for products made with MSM, producers must implement an approved quality control system. The system must provide adequate controls to assure that MSM production is in accordance with good manufacturing practices. These controls include procedures for periodic sampling to assure that products made with MSM are in compliance with the standards. According to the June 1982 regulatory impact analysis, the yearly costs for an average plant to operate a quality control system for products made with MSM would be about \$12,000. Because an approved quality control system is not required to produce products made with MSP, producers can avoid this expense.

In its June 1982 regulatory impact analysis, USDA estimated that only 2.3 million pounds of MSM was produced in 1979 as

⁴ Price ranges are based on minimum and maximum lean trimming prices.

compared with a potential production of 351.7 million pounds. In 1979 330 million pounds of MSP was produced. The major reason given in the impact statement for the reduced production of MSM was labeling requirements on products made with MSM. Also, meat producer associations have stated that consumers are reluctant to buy products with labels stating the product contains powdered bone.

The 1978 standards and labeling requirements on MSM, which were in effect during 1979, included (1) standards on maximum fat and minimum protein, (2) a requirement that MSM be listed in the ingredient statement, and (3) a requirement that label qualifying statements next to the product name state that the product was made with MSM and the percent of powdered bone content of the product. In July 1982 the label qualifying statement next to the product name was deleted and the percent of powdered bone statement was replaced by a statement on the amount of calcium. These revised labeling requirements may make MSM products more saleable.

STANDARDS ARE NEEDED ON COOKED POULTRY SAUSAGES

FSIS establishes product standards on the types and amounts of ingredients that products can contain to preserve nutritional quality and assure the public that it is receiving uniformity and consistency traditionally associated with those products. For cooked meat sausage products, FSIS has established standards on the maximum fat and added water these products can contain and has established sampling procedures to check the finished products for compliance. However, FSIS has not established similar standards on cooked poultry sausage products nor does it sample and test finished products for compliance. Because of this inconsistent regulatory approach, the public is not assured that it is purchasing cooked poultry sausage products that meet an established level of nutritional quality.

The standards that FSIS has established for cooked meat sausage products, such as beef and/or pork frankfurters and bologna, include limiting the amount of fat to 30 percent and added water to 10 percent. FSIS' rationale for adopting these limits is that more fat or added water than the limits would diminish the protein content and nutritional value of these products.

To assure itself and the public that beef and pork frankfurters and bologna do not contain more than 30-percent fat and 10-percent added water, FSIS has established sampling procedures

for use in the plants. Generally, the FSIS plant inspector will take one sample of beef and/or pork frankfurters and bologna for every 35,000 pounds produced and have the sample analyzed for fat and added water. If the sample result shows the product to be out of compliance with the fat or added-water limits, the inspector will resample or require the plant to rework (reprocess) the product until it is in compliance.

FSIS has not established standards limiting the amount of fat and added water that cooked poultry sausage products, such as chicken frankfurters and turkey frankfurters and bologna, can contain. In discussing the reason why standards, such as limits on fat and added water, have not been established for cooked poultry sausage products, FSIS' Deputy Administrator for MPITS said that FSIS had proposed cooked poultry sausage standards in 1976; however, higher priority issues, such as resolving the carcinogen controversy over nitrites, prevented the adoption of cooked poultry sausage standards. He said FSIS was again considering proposing standards on cooked poultry sausage products. He said that this was being done, in part, because poultry associations had asked FSIS to reopen its proposal on cooked poultry sausage standards.

Although FSIS does not analyze samples of cooked poultry sausage products because it has not established product standards, one plant that produces these products periodically samples and analyzes the products' fat and added-water content for its own information. We reviewed 24 plant sample results on poultry frankfurters and bologna at this plant. These sample results showed the fat content ranged from 17.1 to 21.4 percent and the added-water content ranged from 7.7 to 18.2 percent.⁵

If standards on fat and added water were established, such disparities probably would not take place. Without standards

⁵ To arrive at the percent of added water, the plant personnel analyzed the product's percent of total water and then multiplied the percent of protein times four and subtracted that figure from the total added-water figure. For example, if the total water in the product was 64 percent and the protein was 13 percent, the added-water percent would be 12 percent (64 less 52 (13 x 4) = 12 percent). This formula may not be proper for cooked poultry sausages because of the higher level of water in poultry. Plant officials said the cooked meat sausage formula was used because it is the only standard established by FSIS for cooked sausage products.

and related compliance sampling, FSIS cannot assure the public that it is receiving products that have the same uniformity and consistency.

CONCLUSIONS

The Federal Meat and Poultry Products Inspection Acts' main objectives are to prevent the sale of adulterated and misbranded products to the public. FSIS has not established specific standards on MSP and labeling requirements on products made with MSP to adequately carry out these objectives. Because baby food products can be made from mechanically separated fowl, the baby food products may contain an excessive amount of fluoride, which can be a problem for children while their permanent teeth are being formed. Also, because the public cannot differentiate between products made with MSP and hand-separated poultry and are not alerted to the higher amounts of calcium and cholesterol in MSP, MSP product labels can be misleading.

FSIS has also inconsistently applied product standards to cooked meat and poultry products. Because cooked poultry sausage products do not have fat and added-water standards, the public cannot be assured that it is receiving cooked poultry sausage products that meet a minimum standard of nutritional quality and have the same uniformity and consistency.

We realize that establishing specific standards and labeling requirements on MSP and cooked poultry sausage products will result in an increase in budget outlays during a time of tight budgets and may result in increased costs to consumers who purchase these products. These increased costs cannot be determined. However, we believe it is necessary to protect the public from consuming products that may be adulterated and whose labels may be misleading. We also believe it is necessary to assure the public that it is receiving products that meet a minimum standard of nutritional quality and have the same uniformity and consistency.

RECOMMENDATIONS

We recommend that the Secretary of Agriculture direct the Administrator, FSIS, to establish:

- Specific standards on MSP and labeling requirements on products made with MSP as has been done for MSM and products made with MSM.
- Standards on the maximum fat and added water that cooked poultry sausages can contain and appropriate sampling and testing procedures to measure compliance with the standards.

AGENCY COMMENTS AND
OUR EVALUATION

According to USDA (see app. I), FSIS intends to develop a proposal regarding the regulation of MSP. USDA said that its position has been that it would review the status of MSP after completion of the rulemaking initiated in 1981 on MSM. USDA said that in view of the recent Federal district court opinion upholding several critical aspects of the MSM regulations, FSIS had begun preparation for further rulemaking on establishing regulations on MSP and products in which MSP is used. USDA said that the regulations on MSP may not be the same as those for MSM, since MSM and MSP are different products with different properties.

We agree with USDA that MSP regulations may not be exactly the same as those for MSM. Our recommendation was not intended to imply the same regulations. However, we believe that the regulations that FSIS is preparing for further rulemaking should meet the intent of the Poultry Products Inspection Act.

USDA said that a proposal for establishing standards for cooked poultry sausages was also under active consideration. USDA said that the adoption of these standards may be somewhat different from those recommended in the report. USDA did not elaborate on what these differences may be.

CHAPTER 3

MEAT PRODUCT SAMPLING COULD BE MORE EFFICIENT AND EFFECTIVE

FSIS could be more efficient and effective in sampling processed meat products to determine that the products comply with Federal standards. FSIS takes three kinds of samples: (1) verification samples to measure a plant's process and analytical control for products under a partial quality control system, (2) split samples to measure a plant's accredited laboratory's quality and integrity, and (3) regulatory samples done by FSIS or a plant's accredited laboratory to measure compliance with product standards.

The test results of the verification samples we reviewed showed that the plants' partial quality control systems had good histories of compliance. The results of the split samples reviewed also showed that FSIS had developed sufficient histories of compliance on the accredited laboratories' quality and integrity. However, in cases where major discrepancies existed between FSIS split-sample results and accredited laboratory results, FSIS had not effectively followed its procedures on investigating and resolving these discrepancies. Our review also showed that some out-of-compliance products had entered the marketplace. This was because FSIS field laboratory test results on regulatory samples were not known until after the products left the plants.

VERIFICATION SAMPLES SHOULD BE REDUCED

FSIS records show that nationally about 185 partial quality control systems for fat, added water, and added substance are in effect. Our review of 12 of these systems showed that 11 were working well. If a number of the other systems are working as well as the systems we reviewed, sampling costs could be saved by reducing the frequency for verification samples taken at these plants. Reduced verification sampling would also free the processing inspectors to devote more time to other assigned duties, such as checking the plants' sanitary conditions and their product processing procedures, and help reduce sampling backlogs at FSIS field laboratories.

Of the 15 plants reviewed, 9 had one or more partial quality control systems for fat and added water in cooked sausage, added substance in canned hams, or fat and added water

in fresh pork sausage. A breakdown of the partial quality control systems reviewed follows:

<u>Type of quality control system</u>	<u>Number of plants</u>	<u>Total number of quality control systems</u>
Cooked sausage	6	6
Canned hams	1	1
Cooked sausage and canned hams	1	2
Cooked sausage, canned hams, and fresh pork sausage	<u>1</u>	<u>3</u>
Total	<u>9</u>	<u>12</u>

Our review of the sample results over a 1- to 2-year period¹ covered by these 12 partial quality control systems showed that, in all but one case, the plants had (1) maintained good histories of compliance with FSIS regulations, (2) maintained good analytical control while analyzing the chemical makeup of the products, and (3) in most cases, taken corrective action when sample results were out of compliance with the regulations.

For the one partial quality control system that we considered did not maintain a good history of compliance with FSIS regulations, we found that out-of-compliance products had left the plant although the partial quality control system required that the products be resampled, reworked, or rejected. We noted that for the year ended March 1982, 16 sample results showed products covered by the system to be out of compliance, and in at least seven cases, the products were shipped to consumers without being resampled, reworked, or rejected.

¹ To determine compliance history, we tried to review sampling records over a 2-year period. However, in many cases, both FSIS and plant records were not available for the full 2-year period. Therefore, we reviewed available sampling results up to 2 years.

For the remaining 11 systems, the plants' quality control personnel had taken about 14,615 samples of the products covered by these systems. Only 64 of these samples were not in compliance with FSIS product regulations for fat, added water, or added substance. Plant records showed that for the 64 samples that were not in compliance, the quality control personnel took corrective action in 49 cases by either changing the product formulation process or retaining and reworking the product. In the remaining 15 cases, either no processing change was made or plant records did not indicate the action taken; however, in all 15 cases, the next sample result showed the product was in compliance.

FSIS inspectors, over the same time period, took 829 verification samples to check how well the 11 partial quality control systems were working. In only 24 of the 829 cases did the verification-sample results show the products not to be in compliance. In most of these cases, FSIS inspectors checked the plants' quality control sampling results and prior verification-sample results to see what they showed. In reviewing the plants' results, the FSIS inspectors generally reviewed both the plants' last five sample results and the last five verification-sample results. In 19 of the 24 cases, the last five plant and verification results showed the products to be in compliance and FSIS took no further action. In four cases involving out-of-compliance verification samples at one plant, the regional office staff made an analysis of the plant's partial quality control system and concluded it was operating properly. In the remaining case the inspector increased his sampling frequency.

The following examples are illustrative of plants reviewed that had good partial quality control systems.

--One plant had a partial quality control system for added substance in canned hams. The sample results for approximately a 1-year period showed that the plant's quality control personnel analyzed 846 samples to check compliance on added substance. In all cases, the samples were in compliance. During the same period, the FSIS inspector took 37 verification samples and again, in all cases, the sample results showed that the product was in compliance.

--Another plant had a partial quality control system for fat and added water in cooked sausage. The sample results for the year ended March 1982 showed that the plant's quality control personnel had analyzed 1,648 samples and only 11 samples were not in compliance. For 10 of the 11 out-of-compliance samples, the plant

made processing changes, and for the 1 sample where the plant did not, the next sample result showed the product to be in compliance. During the same period, FSIS inspectors took 51 verification samples, and in all cases, the sample results showed the product to be in compliance.

--Another plant had a partial quality control system for added substance in canned hams. The sampling records for about a 17-month period ended April 1982 showed that the plant's quality control personnel analyzed 1,092 samples to check compliance on added substance. In all cases, the samples were in compliance. During the same period, the FSIS inspectors took 123 verification samples and again all samples were in compliance.

The FSIS processing inspectors at the plants we visited said that verification samples could be reduced in plants that had good histories of compliance without any major effect on measuring the plants' partial quality control systems. The inspectors at two plants producing cooked meat sausage said that the plants had good histories of compliance and that the sampling frequency could be reduced from weekly to monthly. At a third plant an inspector who submitted 89 verification samples of canned hams during a 2-year period said it was unnecessary to sample as frequently as he does. An inspector at a fourth plant said that a 50- to 75-percent decrease in the number of samples he submits would cause no change in the plant's operation or in program results.

In addition, the processing inspectors would continue to have other controls available to them to determine whether the products are in compliance with the regulations. The inspectors would continue to monitor the partial quality control systems on a daily basis and could review the plants' quality control system records whenever warranted. The inspectors would also continue to monitor daily the plants' manufacturing processes and procedures used in formulating and producing the products under partial quality control systems.

Each verification sample FSIS analyzes costs about \$32.00 (\$28.00 for sample analysis and \$4.00 in mailing costs). If sampling for the 11 partial quality control systems reviewed that showed good histories of compliance were reduced, for example, from once a week to once every 2 months, FSIS could save about \$23,456 in direct sampling costs over a 1- to 2-year period. A review of FSIS records showed that nationwide about 185 partial quality control systems are approved for fat, added water, and added substance. If a number of these systems are

working as well as the systems we reviewed, sampling costs could be saved by reducing the frequency for verification samples at these plants. Reducing sampling would also free the inspectors to devote more time to other assigned duties.

In a June 10, 1982, letter to the FSIS Administrator, we asked whether the frequency for verification samples taken and analyzed by FSIS could be reduced for plants with good histories of compliance and, if so, what the frequency could be reduced to. In a July 7, 1982, response, the Administrator said FSIS hoped to reduce the frequency for verification samples for plants with good compliance histories on the operation of their partial quality control systems. The Administrator said that he was considering two options for reducing verification samples. One would be to prepare a procedure that can be implemented quickly based on FSIS' best professional judgment; however, he said the option could be error prone and subjective. The second option would be to establish a statistical sampling plan that would provide a high degree of confidence on the effectiveness of the partial quality control system but would require a substantial commitment of resources. The Administrator did not say what the samples should be reduced to.

SPLIT SAMPLES SHOULD BE REDUCED

FSIS has approved about 200 private laboratories to analyze regulatory samples. To check the laboratories' quality and integrity, FSIS splits some samples, with half sent to its own laboratory and half sent to an accredited laboratory. The results are then compared. Generally, FSIS splits one sample for every four samples an accredited laboratory tests. Seven of the eight accredited laboratories we reviewed had such good histories of compliance that FSIS could reduce the number of split samples analyzed.

To judge the accredited laboratories' integrity and quality, FSIS has developed guidelines to determine minor and major discrepancies between its laboratory results and those of the accredited laboratories. The guidelines cover protein, total water, fat, salt, and added substance. If an accredited laboratory's results, over time, do not show more than 25 percent minor discrepancies or 5 percent major discrepancies with FSIS field laboratory results, then the accredited laboratory is considered in good compliance.

Of the plants reviewed, eight had accredited laboratories. FSIS records show that it tested 841 split samples from seven of the eight accredited laboratories for the 2-year period ended December 31, 1981. Split-sample results for the eighth accredited laboratory were not available for the complete 2-year

period. Our analysis of the results from the seven accredited laboratories showed that about 11 percent of the samples were in the minor discrepancy category and about 3.5 percent were in the major discrepancy category, both well within FSIS guidelines.

At the time of our plant visits from February through April 1982,² neither the FSIS processing inspectors assigned to the seven plants nor the plants' personnel had been contacted by FSIS headquarters or field laboratory officials to discuss the results of any split-sample tests. Both the FSIS inspectors and plant personnel assumed that this meant the accredited laboratories were doing a good job. An FSIS headquarters official responsible for comparing and analyzing the split-sample results on these seven accredited laboratories told us that the laboratories' performance had been adequate and no formal contacts or reviews had been made during the 2-year period.

Since FSIS has continually taken and analyzed split samples at the seven accredited laboratories and apparently has been satisfied with the accredited laboratories' results, FSIS has developed sufficient histories of compliance on the accredited laboratories' quality and integrity and should be able to reduce the number of split samples tested. Since about 200 accredited laboratories are used to analyze regulatory samples, a reduction in the number of split samples taken for laboratories with good histories would result in savings to FSIS. Because the number of split samples tested depends on the number of regulatory samples tested, and may vary based on plant production and product type, an overall reduction rate cannot be computed.

In our June 1982 letter to the FSIS Administrator, we asked whether the number of split samples taken and analyzed by FSIS could be reduced for accredited laboratories that FSIS has already established as having high integrity and good quality. We also asked the Administrator what the split samples for these laboratories could be reduced to. In his July 1982 response, the Administrator said he was actively considering reducing

² Subsequent to our visits, FSIS field laboratory personnel made unannounced, prescheduled reviews at two of the accredited laboratories we visited. Both FSIS and plant officials said the reviews showed the accredited laboratories to be in good compliance.

split samples for accredited laboratories with good compliance records. He said that FSIS was developing a sampling algorithm (a step-by-step procedure for accomplishing a goal) to determine the number of split samples to be taken from each accredited laboratory. The Administrator said that this sampling technique was needed because

- accredited laboratories had developed their good histories because FSIS was cross checking their results,
- FSIS measures an accredited laboratory's compliance history on the basis of the most recent 40 samples and for some laboratories the 40 samples may take years to generate, and
- split-sample reductions could lengthen the period needed to find discrepancies on laboratories with previously good records.

We believe that sufficient histories of compliance have already been established for a number of the accredited laboratories and that split samples should be reduced at those laboratories. For the eight laboratories that we reviewed, seven had continual sampling for the 2-year period and all seven had good histories of compliance. We are not suggesting that cross checks be eliminated, but that they be reduced.

In addition, the number of split samples taken at these seven laboratories for the 2-year period ranged from 47 to 287, all above the 40-sample criterion that the Administrator said was needed to measure compliance. Although the Administrator's concern that reducing the number of split samples could substantially lengthen the period needed to find discrepancies, the length of time taken to find discrepancies was not a factor since FSIS had not effectively investigated and resolved the discrepancies it had found.

Need to resolve discrepancies between FSIS and accredited laboratory sampling results

FSIS has established procedures to investigate and resolve major discrepancies between its laboratory results and accredited laboratory results on split samples. However, our review showed that when major discrepancies occurred, FSIS made no attempt to investigate and resolve them. As a result, FSIS did not know which laboratory used the proper handling and/or analytical procedures in determining sample results.

Split samples are tested for protein, total water, fat, added water, or added substance. The number of tests made depends on the product. Frankfurters are tested for protein, total water, fat, and added water. Canned hams are tested for protein, total fat, water, and added substance. A major discrepancy occurs when the results for the accredited laboratory and the FSIS field laboratory for either protein, total water, fat, added water, and/or added substance differ by a certain percent. The percent varies depending on the item being tested.

When a major discrepancy occurs, FSIS field laboratory personnel are to investigate the discrepancy and if they cannot easily resolve or explain it, they are to contact the accredited laboratory personnel by telephone and attempt to obtain corrective action. If the field personnel are unsuccessful, FSIS headquarters initiates further action, including an onsite review of the accredited laboratory. Ultimately, the accredited laboratory could lose its accreditation.

On the 841 split samples tested on a continuous basis over the last 2 years at the seven accredited laboratories we reviewed, 2,664 tests were performed for protein, total water, fat, and/or added substance. Of these, 94, or about 3.5 percent, represented major discrepancies. These major discrepancies do not necessarily mean that the products tested were out of compliance but only that major differences existed between the accredited laboratories' and the FSIS laboratory's results. As stated on page 25, at the time of our plant visits, none of the FSIS processing inspectors assigned to these seven plants or the plants' personnel had been contacted by FSIS headquarters or field laboratory officials concerning the results of the split-sample tests.

MORE TIMELY SAMPLE RESULTS ON PRODUCT COMPLIANCE NEEDED

FSIS takes and analyzes product samples to determine that products leaving the processing plants are complying with established product standards. However, products which were sampled by an FSIS field laboratory had sometimes left the plants before the regulatory-sample results were known. As a result, some out-of-compliance products had entered the marketplace and consumers may not have received what they paid for.

Regulatory samples are chemically analyzed to determine their compliance with product standards. The samples are submitted for analysis to either a plant's accredited laboratory or, if the plant does not have an accredited laboratory or does not elect to use an accredited laboratory in the area, to an

FSIS field laboratory. Generally, only the larger volume plants have accredited laboratories.

Regulatory samples were taken at 13 of the 15 plants visited.³ Samples for 7 of the 13 plants were submitted to FSIS' midwestern field laboratory while samples from the other 6 plants were generally analyzed by the plants' accredited laboratories. Of the 1,995 samples reviewed at the 13 plants, 1,743 were analyzed by the accredited laboratories while 252 were analyzed by FSIS' midwestern field laboratory. More regulatory samples are analyzed at the accredited laboratories as compared with the FSIS field laboratory because accredited laboratory plants produce a higher volume and more types of products and thus require more sampling.

For the 252 samples analyzed by the FSIS midwestern field laboratory, the plant inspectors did not receive the sample results for between 6 and 53 days with an average of 17 days after the samples were taken. The accredited laboratory results took 1 to 2 days. The long delay in receiving FSIS field laboratory results usually means the product leaves the plant before the FSIS field laboratory results are known. The inspectors at the accredited laboratory plants said they receive the sample results in sufficient time to resample or rework out-of-compliance products.

Of the 252 samples analyzed by the FSIS midwestern field laboratory, 8 samples were out of compliance with product standards for either excess water, fat, or added substance. In four of the eight cases, the plant inspectors indicated that the products had left the plants before the sample results were known but this could not be conclusively documented. In the four remaining cases, the products had left the plants and presumably had been marketed before the plant inspectors received the out-of-compliance sample results. As a result, the out-of-compliance products could not be resampled or reworked and entered the marketplace. The following examples illustrate this point.

³ One plant produced only poultry products for which regulatory samples are not required, as discussed previously, and a second plant's total product was under a partial quality control system that required only verification samples.

--An inspector collected a sample of Italian sausage (a fresh pork sausage), which is limited to 35-percent fat, on December 1, 1980, and submitted it to the FSIS field laboratory for analysis. The FSIS midwestern field laboratory received the sample on December 4. The analysis began on December 9, was completed December 19, and showed the product to contain 40-percent fat. The date the inspector received this result was not documented. However, the inspector stated that product from this plant is usually shipped within 1 to 2 days after processing is completed and that none of the product was at the plant for the inspector to retain.

--An inspector collected a sample of fresh pork sausage, which is limited to 3-percent added water, on May 21, 1980, and submitted it to the FSIS midwestern field laboratory for analysis. The FSIS field laboratory received the sample on June 4. The analysis began on June 4, was completed on June 6, and showed that the product contained 4.1-percent added water. The date the inspector received the sample result was not documented. However, the inspector said that the product from this plant is usually shipped within 2 to 3 days after processing is completed and that the results were received too late to retain the product.

We asked the inspectors what purpose the regulatory samples serve if the product is entering the marketplace before the sample results are known. They said the regulatory samples' main purposes are to develop a plant's history of compliance and to take corrective actions on products produced in the future. The inspectors further said that other controls are available to them, such as reviewing the plant's product processing procedures, to help assure that the products are in compliance.

We visited the FSIS midwestern field laboratory to determine why sample results take so long to analyze. We were told that from sample receipt to completion takes from 1 day to more than 3 weeks depending on sample backlog, type of analysis, sample priorities, and available staff. For the period January 1981 through March 1982, the sample backlog averaged 307 per week and ranged from 100 to 643. Because of the backlog at the FSIS midwestern field laboratory and additional mailing time from the plants to the laboratory, out-of-compliance products had entered the marketplace.

CONCLUSIONS

FSIS continues to analyze verification samples about once a week on partial quality control systems that have good histories of compliance. It also continues to analyze split-sample results regularly even though it has already developed histories of compliance on the accredited laboratories' quality and integrity. Reductions in both these samples would result in sampling cost savings to FSIS. Reduced sampling would free the processing inspectors to devote more time to other assigned duties and help reduce laboratory backlogs.

FSIS has not effectively enforced its procedures on investigating and resolving major discrepancies on split-sample results. Without this enforcement, FSIS has no way of knowing which laboratory, FSIS' or the accredited, used the proper handling and/or analytical procedure in determining sample results, thus diminishing the value of taking split samples.

The results of regulatory samples analyzed by the FSIS midwestern field laboratory were not always known to the plant inspectors before the products covered by the samples left the plants. As a result, products which samples showed to be out of compliance could not be resampled or reworked and had entered the marketplace. The main reason why the FSIS midwestern field laboratory results were not known before the products left the plants was that the plant inspectors had not received the sample results, on average, for 17 days and plants cannot keep their products tied up for this long a period. The main reason for the long delay before the inspector received the sample results was sample backlogs at the FSIS midwestern field laboratory. This problem did not exist when accredited laboratories were used to perform regulatory-sample analysis because their results were known to the inspectors within 1 to 2 days.

RECOMMENDATIONS

We recommend that the Secretary of Agriculture direct the Administrator, FSIS, to:

- Reduce verification sampling at plants with partial quality control systems that have good histories of compliance. Also, reduce split sampling at plants that have accredited laboratories with good histories of compliance.
- Enforce its procedures on investigating and resolving major discrepancies on split-sample results between FSIS field laboratories and the accredited laboratories.

--provide inspectors with timely sample results on product compliance. This could be accomplished by reducing the backlog of samples that need to be analyzed at the FSIS field laboratories. By reducing the number of samples as recommended above, fewer samples would be analyzed by the FSIS field laboratories and the sample results would be returned to the inspectors faster. FSIS could also encourage plants to use nearby accredited laboratories.

Budgetary impact of our recommendations

All of the above recommendations address increased efficiency in FSIS operations and would generally result in savings, reductions in backlog, and increased consumer protection. Since we do not know what the verification-sample frequency and number of split samples would be reduced to at plants with good histories of compliance, we cannot estimate the budgetary savings that would accrue from our recommendations.

Any budgetary savings would accrue to the Department of Agriculture, FSIS, Salaries and Expenses appropriation (05-83) 12-3700 in the Consumer and Occupational Health and Safety (554) budget subfunction. The Senate Committee on Agriculture, Nutrition, and Forestry and the House Committee on Agriculture have jurisdiction over these programs.

AGENCY COMMENTS AND OUR EVALUATION

USDA agreed with our recommendation to reduce verification and split sampling at plants with good histories of compliance. According to USDA (see app. I), FSIS had already begun to take action. It said an option paper for statistically determining sampling frequency while maintaining sampling as a deterrent was under consideration.

USDA also agreed with our recommendation that FSIS enforce its procedures on investigating and resolving major discrepancies on split-sample results between its field laboratories and the accredited laboratories. USDA said that FSIS recognized these problems and now had three accredited laboratory reviewers following up on all major discrepancies. According to USDA, FSIS was completing work on formal regulations for its accredited laboratory program that would enable it to take effective action when accredited laboratories are not performing satisfactorily.

USDA said that our recommendation to reduce the amount of out-of-compliance products reaching the marketplace was unnecessary based on the findings presented in the report. Its major disagreement with the recommendation was that it "misrepresented" the record FSIS has achieved in consumer protection. FSIS believes its current procedures are very effective in assuring that products in the marketplace comply with the fat, added-water, and added-substance requirements. According to USDA, the current system is efficient for both the agency and the industry. USDA also said that FSIS cannot increase the number of accredited laboratories used in analyzing regulatory samples because the number and use of these laboratories is not under its control. However, it said FSIS does encourage the use of accredited laboratories on a voluntary basis and expects to see expansion of these laboratory services as interest in quality control programs grows.

Based on USDA's comments, we have clarified this recommendation. We agree with USDA that our suggestion emphasizing out-of-compliance products could have been interpreted as misrepresenting FSIS' record on sampling finished products for regulatory compliance. Therefore, we clarified the recommendation to emphasize the need for more timely sample results. Since the number and use of accredited laboratories is not under FSIS' control, we deleted that portion of our recommendation that FSIS increase the number of these laboratories in analyzing regulatory samples.

However, we disagree with USDA that our recommendation is unnecessary based on the report's findings. USDA said our findings showed that, in four of the eight sample cases cited for out-of-compliance products, the sample results did reach the inspector before the products represented by the samples entered the marketplace. USDA said also that the two examples cited in the report on out-of-compliance samples did not represent a health hazard and did not show a substantive loss of control over product formulation.

We believe the findings presented in the report clearly demonstrate a need for inspectors to receive sample results in a more timely manner. We said that in four of the eight out-of-compliance sample cases, the products left the plants before the plant inspectors received the results. This was misinterpreted by USDA to mean that in the other four cases the inspector received the sample results before the products left the plants. This was not true. The four cases we cited were based on conclusive evidence that the products left the plants before the plant inspector knew the sample results.

In the four remaining cases, the plant inspectors indicated that the products had also left the plants before the sample results were known but this could not be conclusively documented. In fact, all seven FSIS inspectors who worked in the seven plants that submitted their regulatory samples to the FSIS mid-western field laboratory said that products usually left the plants before the sample results were known. Therefore, indications are that the sample results for these four cases were not known before the products left the plants. This was clarified on page 28 of the report.

USDA also commented that the two examples cited in the report on out-of-compliance samples did not represent a health hazard and did not show a substantive loss of control over product formulation. However, the purpose of regulatory samples is not to determine whether the product represents a health hazard (FSIS takes other samples to determine whether a product represents a health hazard) but to measure a product's compliance with fat, added-water, and/or added-substance standards. In commenting on the draft report, USDA said that if a product does not conform to a standard, it should be considered misbranded. Since the two examples cited clearly show the products to be out of compliance with the products' standards, they should be considered misbranded and should not have reached the marketplace. To help prevent misbranded products from reaching the marketplace, FSIS should initiate action so that inspectors are informed more quickly of out-of-compliance samples.

Furthermore, we believe the examples cited show a loss of control over product formulation, which the inspectors should know as soon as possible so corrective actions can be implemented. In the two examples cited on page 29, the Italian sausage contained about 14 percent more fat and the fresh pork sausage contained about 33 percent more added water than the products' standards allowed.



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D. C.
20250

JAN 17 1983

Mr. J. Dexter Peach
Director, Resources, Community and Economic
Development Division, GAO
4th and G Streets, NW
Washington, DC 20548

Dear Mr. Peach:

Thank you for the opportunity to comment on your draft report, "Federal Regulation of Meat and Poultry Products--Increased Consumer Protection and Efficiencies Needed." The Food Safety and Inspection Service (FSIS) agrees with the general direction and intent of most of your recommendations. However, we have a number of general comments and suggestions regarding the report's findings and analysis, and a serious disagreement with one of your conclusions. These are discussed below and incorporate the views of the Assistant Secretary for Marketing and Inspection Services and USDA's Office of Budget and Program Analysis. We have noted a number of corrections and clarifications in an enclosure which is keyed to specific pages of your draft report.

Need For Additional Standards and Labeling Requirements

FSIS intends to develop a proposal regarding the regulation of the product that has been marketed as "mechanically deboned poultry" (MDP, referred to as MSP in your text). However, your report, especially in the digest, leaves the impression that MDP is unregulated, and that FSIS has not addressed the potential concerns raised by MDP. In fact, regulations governing MDP have been in effect since 1969. When technology for producing MDP with low bone content and extremely small bone particle size had been developed, USDA imposed a maximum limit of 1 percent on the bone solids content of MDP. Among other things, this maximum protects against increases (as compared with hand-trimmed poultry products) in the amount of minerals such as fluoride that may tend to concentrate in bone. The 1 percent bone limit is achieved by limiting the calcium content to 0.175 percent for MDP made from young chickens and 0.235

[GAO COMMENT: The report digest has been modified to include a statement on the 1969 regulations that imposed a 1-percent bone limit on products made with MSP. However, we do not believe that the 1-percent bone limit is sufficient. As stated in the report, a 1979 study on MSP's health and safety aspects, which included products covered by the 1969 regulations, concluded that (1) MSP made with fowl had a high fluoride content like MSM, (2) calcium levels of products using 100-percent MSP can be up to twice as high as those for products made with MSM because of MSM's 20-percent limit, and (3) MSP consumption could pose problems for persons who must control their cholesterol intake. Because of the study's conclusions, we believe FSIS needs to establish specific standards and labeling requirements on MSP and products made with MSP.]

percent for MDP made from turkeys and mature chickens. USDA also considers bone particle size in evaluating the equipment to be used in producing MDP. MDP is subject to the general requirements for the labeling of poultry products. For example, MDP is declared in the ingredient statements of finished products (along with the other ingredients used) as "chicken" or "turkey" where parts such as skin and fat are not present in excess of natural proportions, and it is labeled as "chicken meat" or "turkey meat" where no skin or fatty tissue are included. We believe this information should be reflected in your evaluation of the current regulatory situation.

We also suggest that you consider modifying your text to include a more accurate description of the regulation of the livestock product prepared by the mechanical separation and removal process. This product, "Mechanically Separated (Species)" (MS(S), referred to as MSM in your text), came into production after MDP was developed. In 1976, USDA published a proposal and an interim rule for this product similar in approach to the regulation of MDP. However, a Federal district court held that the issuance of the interim rule violated the Administrative Procedure Act and stated that this product was not "meat" as traditionally defined because of its bone particle content. As a result, USDA revoked the interim rule and developed a revised proposal.

The final rule published in 1978 took into account the information compiled during the rulemaking, the Court's opinion, and subsequently acquired information from scientific research in the areas of nutrition and toxicology. Among other things, USDA established a definition and standard for the ingredient. Products subject to a definition and standard must be identified by the specified name. Therefore, MS(S) must be separately declared in the list of ingredients on labels of products in which it is used.

In 1981, USDA initiated another rulemaking to consider possible amendments to certain of the 1978 regulations. The final rule issued in June 1982 retained many of the requirements established in 1978, including the restriction on the level of use to not more than 20 percent of the livestock and poultry product portion of any meat food product. The final rule was challenged in Federal district court by several consumer-oriented public interest groups which objected to the change of the ingredient name from "MP(S)P" to "MS(S)" and to the changes in the labeling of finished meat food products.

[GAO COMMENT: The report was modified to include a statement that the 1982 regulations retained many of the 1978 requirements. We believe the remainder of the report's description of the regulation of MSM is accurate.]

On December 1, 1982, the district court upheld the June 1982, final rule and found in favor of USDA on each of the misbranding, adulteration, and Administrative Procedure Act issues involved in the case. A notice of appeal in this case has been filed.

[GAO COMMENT: The report was updated to include the court's decision and the notice of appeal.]

USDA's position has been that it would review the status of MDP after completion of the rulemaking initiated in 1981 on MS(S). In view of the recent Federal district court opinion upholding several critical aspects of the MS(S) regulations, USDA has begun preparations for further rulemaking on the regulation of MDP and products in which it is used. However, requirements for MDP and products in which it is used may not be the same as those for MS(S), since MS(S) and MDP are different products with different properties.

A proposal for standards for cooked poultry sausages is also under active consideration. The Department did propose standards in 1976; but it was the policy of the previous Administration to give priority to the nitrite issue, and so the Department did not complete rulemaking on cooked poultry sausages. As mentioned in your report, FSIS has been petitioned by a major trade association and has resumed work on a proposal. Again, the approach may be somewhat different from that recommended in your report.

Product Sampling Can be More Efficient and Effective

We must take issue with your third recommendation in this section since it seriously misrepresents the outstanding record of consumer protection this agency has achieved.

Your recommendation calls for FSIS to minimize the amount of out-of-compliance product reaching the marketplace. This suggests to readers that FSIS has a problem controlling out-of-compliance product. However, the facts presented in the body of the report show that just the opposite is true. Out of 252 samples analyzed for excess water, fat, or added substances, 244 (or almost 97 percent) were in compliance. This is an outstanding record for any regulatory program. The recommendation goes on to suggest that faster turnaround time on laboratory samples is necessary. However, in 4 of the 8 cases you cited, the sample results did reach the inspector before the product represented by the sample had entered commerce. Two of the eight cases are described in detail--neither case represented a health hazard; neither showed substantive loss of control over formulation. From the findings presented in your report, I conclude that the current procedures are very effective in assuring that products in the marketplace comply with the fat, water, and added substance requirements. Therefore, the recommendation is unnecessary.

Furthermore, it is not true that either efficiency or effectiveness would be improved by holding products at the plant until laboratory results are available. The current system is efficient for both the agency and the industry. The industry does not incur the costs of routinely holding products until sample results are returned, and the agency can prioritize work at the laboratories for the maximum benefit. Effectiveness would not be improved either, as discussed above.

[GAO COMMENT: Our report did not advocate that products be held at the plant until laboratory results are available. We realize the efforts and additional costs that the industry would incur by routinely holding products until sample results are known to the inspectors. We believe that if the actions recommended on page 31 are implemented by FSIS, the inspectors will receive the sample results in a more timely manner and out-of-compliance products entering the marketplace would be minimized.]

The number and use of accredited laboratories is not under our control. However, we do encourage their use on a voluntary basis, and we expect to see expansion of private laboratory services as interest in quality control programs grows.

[GAO COMMENT: This is addressed on page 32 of the report.]

We have already begun to take action on your first two sampling recommendations. We support reducing verification sampling at plants with good partial quality control systems. However, FSIS is approaching the issue from a consumer protection perspective, not strictly from a cost perspective, as your report does. Sampling has deterrent value. At some point, a reduction in the frequency of sampling reduces the deterrence. An option paper for statistically determining sampling frequency while maintaining the deterrent value of sampling is under consideration in the agency.

[GAO COMMENT: We did not approach the issue of reduced sampling strictly from a cost perspective. As is stated throughout chapter 3 and in our recommendation, reduced sampling should take place only for partial quality control systems and accredited laboratories that have good histories of compliance.]

FSIS has recognized the problems with resolving major discrepancies in results between FSIS field laboratories and accredited laboratories. We now have three accredited laboratory reviewers who follow up on all major discrepancies. In addition, we are completing work on formal regulations for the accredited laboratory program. These regulations will enable us to take effective action when accredited laboratories are not performing satisfactorily.

As your report illustrates, FSIS is increasingly challenged by technological innovations, scientific advances, and public expectations. In response, we are working on a number of regulatory initiatives. We are pursuing these initiatives with caution so our primary goal, consumer protection, is not sacrificed.

We look forward to receiving your final report.

Sincerely,

A handwritten signature in cursive script, appearing to read "Donald L. Houston".

Donald L. Houston
Administrator

Enclosure

Detailed Comments on CAO Draft Report, "Federal Regulation of Meat and Poultry Products--Increased Consumer Protection and Efficiencies Needed"

The following comments are keyed to specific pages. Please note that the same errors may appear in several places in your text.

1. The report uses the term "mechanically separated meat." The correct name of the product as established by regulation is "Mechanically Separated (Species)" (MS(S)), as in "Mechanically Separated Beef." No similar action has been taken regarding the mechanically separated poultry ingredient. This product has been referred to as "mechanically deboned poultry" (MDP) within the meat and poultry industry.

2. The report fails to clearly distinguish between MS(S) and MDP--which are products used as ingredients--and multi-ingredient finished meat food and poultry products that contain these ingredients. For example, the report uses terminology such as "MSM products" or "MSP products" and "made from" MSM or MSP in ways which imply that MS(S) and MDP generally or frequently are the only ingredients in finished products. The failure to distinguish between ingredients and finished products also confuses important differences in the regulatory issues. For MS(S), the standard-setting question has focused on whether there should be a separate definition and standard for the ingredient, and if so, what its provisions should be. The labeling question has focused on what information should be required on finished product labels when the ingredient is used. We suggest clarification in the use of this terminology and in references to "MSM standards and labeling requirements," or "requirements on MSM (or MSP) products" (e.g., pages ii, iii, 6, 7, 12, and 18).

3. Page i, paragraphs 1-2: Assuming the report is referring to the ingredients MS(S) and MDP in paragraph 2, the question has been whether their composition as compared with that of hand-trimmed ingredients raises potential problems. Concern focused initially on bone content, particularly potential increases in the amounts of certain substances that may tend to concentrate in bone such as the essential nutrients calcium and fluoride. Therefore, USDA established limits on bone solids content when each ingredient was introduced.

Additional issues were raised when the regulation of the livestock product ingredient was considered, particularly regarding finished product quality. However, it was not until 1978 (not 1974) that USDA decided to establish labeling requirements that distinguish between finished products containing the livestock product ingredient and those not containing it. When USDA scientists in consultation with other experts evaluated health and safety aspects of the use of the poultry product ingredient, they took into account determinations made in 1978 regarding MS(S). The 1979 report of their evaluation did recommend further regulatory action. However, they treated MDP as a distinctive ingredient and their recommendations reflect this. For example, the conclusions regarding fluoride content and limitations on use differed from those reached regarding MS(S).

4. Page ii, paragraph 2: As with other essential nutrients, there is a range within which intakes of fluoride are both adequate and safe and beyond which adverse effects can occur. In 1978, USDA's concern with MS(S) was that the appearance of the tooth enamel, not health, might be adversely affected.

[GAO NOTE: Page numbers have been changed to agree with the final report.]

We suggest changing the phrase "up to 8 years old" to "while their permanent teeth are being formed". (See also pages 11 and 18.) The fowl issue related to baby food, which is not generally consumed by children past infancy. Young children who do not eat baby food are protected by the use limits and maximum calcium requirements, which limit bone where fluoride and other substances may tend to concentrate.

5. Page ii, paragraph 3: The definition and standard for MS(S), the limitations on its use, and the labeling requirements for finished products containing it as an ingredient were not based on its cholesterol content as compared with that of meat. When the 1978 requirements were established, USDA believed that the cholesterol content of MS(S) varied within the same range as that of product made by traditional, hand-trimming techniques. Additional information compiled and evaluated during the 1981-82 rulemaking indicated differences in cholesterol content and influenced USDA's decision to withdraw the portion of its 1981 proposal that would have allowed one category of MS(S) to be used at higher levels. USDA decided not to engage in further rulemaking on the issues involved at this time, in large part because the existing restriction on the usage level is unlikely to constrain production.

Similarly, the purpose of the calcium content limit in the definition and standard for MS(S) is to control the amount of hard bone and accompanying substances in MS(S), and not to control the amount of the essential nutrient calcium that is provided by meat food products. The calcium content labeling of finished products involves a different issue: USDA's concern that the small group of Americans on calcium-restricted diets not be misled where there are meaningful increases in the calcium content of finished meat food products. (The general public can distinguish between finished products that do and do not contain MS(S) on the basis of the list of ingredients on their labels.) The 1982 final rule requires information be provided on the per serving calcium content of finished products where MS(S) contributes 20 mg or more of calcium to a serving (unless the amount declared would not differ from the amount that would be declared if only hand-trimmed ingredients were used or the calcium content would be 20 percent of the U.S. RDA or more if only hand-trimmed ingredients were used). Page 10 of the report misstates the calcium labeling requirement.

6. Page 6, paragraphs 1-2: USDA concluded MS(S) differs sufficiently in its consistency and composition from "meat" that it cannot be regarded as falling within that category as traditionally defined. The definition and standard for MS(S) control its composition and the regulations also limit its use. USDA has not established standards for finished meat food products because of the development of MS(S), although modifications have been made in certain existing standards to indicate that use of MS(S) is permitted.

The labeling requirements imposed by USDA are designed to prevent any type of misbranding. For example, as indicated above, once a definition and standard is established for a product, it must be identified by the specified name. Therefore MS(S) (e.g., "Mechanically Separated Beef") must be separately declared in the ingredient statements of finished meat food products in which it is used. This is not a special labeling requirement, and it applies to the listing of ingredients on the labels of both non-standardized and standardized meat food products.

7. Page 7, paragraph 3: The ingredient is MS(S). Its content of certain substances, such as the minerals calcium and fluoride, may differ from that of meat due to the presence of bone, including bone marrow, as a result of the manufacturing process. The controversy has centered around potential compositional differences, and the regulation of MS(S) and its use as an ingredient.
8. Page 8, paragraph 2, sentence 1: The regulations define MS(S) as the finely comminuted product resulting from the mechanical separation and removal of the bone from attached skeletal muscle.
9. Page 9, paragraph 4: The interim regulation took effect when it was published. The Court held that this violated the Administrative Procedure Act and issued a preliminary injunction prohibiting USDA from giving further effect to the interim regulation.
10. Page 10, paragraph 2: Change to read "...20 percent of the livestock and poultry product portion..."
11. Page 11, paragraph 3: The health and safety report stated that intakes of fluoride from MDP made from fowl could be excessive. It did not say that the baby foods could contain excessive fluoride. See page 8 of the health and safety report for an accurate summary of the conclusions and recommendations.
12. Page 12, paragraph 2: The report was a staff report prepared by USDA scientists in conjunction with other experts. Your three point summary of their recommendations on MDP made from fowl in baby food is not accurate. It confuses consumption information and projections of maximum intakes. It also confuses starting materials, ingredients, and finished products.
13. Page 12, paragraph 4: As indicated above, USDA does not restrict the usage level of MS(S) because of differences in cholesterol content. In 1978, USDA determined that the 20 percent limitation on MS(S) was optimum in that it allows for the use of the ingredient without diminishing the quality and overall expected characteristics of finished products and does not result in any health or safety problems. Relative cholesterol contents also did not serve as the basis for any labeling requirement established in that rulemaking.

The calcium content labeling requirement established in 1982 does not alert consumers to higher amounts of calcium; instead information on the calcium content of finished products (based on all of their ingredients) is provided where appropriate. Finally, the conclusion that "these same concerns apply to MSP products," yet USDA "has not established additional standards and labeling requirements" is inconsistent with the summary of the health and safety report's conclusions, with the existence of the bone solids content limit on MDP, and with the differences in the calcium content of MDP as compared with MS(S).

14. Page 12, paragraph 3: As a standardized product, MS(S) must be listed by the name specified in its definition and standard. What USDA said in 1978 was that this product "is not meat and will be a standardized product following publication of this rule. Therefore, it must be listed separately from meat...."

[GAO COMMENT: Paragraph deleted due to editorial changes.]

15. Page 13, paragraph 5: We have several comments on this paragraph. Only those poultry products (certain cooked sausages) in which use of MDP has reached the highest levels were reviewed. MDP is used at much lower levels (including levels as low as 2 to 3 percent) in some poultry products. Also, the evaluation done in the health and safety report attempted to calculate the maximum calcium contribution that MDP could make to U.S. diets if all processed poultry consumed were MDP with the maximum permitted calcium content. This is not a comparison of products containing MDP with products containing MS(S). (Also, the health and safety report said "at most" twice the calcium.) Even if one assumes that a poultry product is 100 percent MDP and a similar meat food product is 20 percent MS(S), and the MDP and MS(S) have the maximum permitted calcium contents, MDP will not contribute twice as much calcium as is contributed by MS(S) because the maximum calcium permitted in different types of MDP (0.175 percent and 0.235 percent) is quite a bit lower than that permitted in MS(S) (0.75 percent). Thus, MDP made from young chickens (about 65 percent of the MSP produced in 1979) used at the 100 percent level could contribute about 1.2 times as much calcium as MS(S) used at the 20 percent level; and MDP made from turkeys and mature chickens (about 35 percent of the MSP produced in 1979) used at the 100 percent level could contribute about 1.6 times as much calcium as MS(S) used at the 20 percent level.

16. Page 14, paragraph 4: Add to the end of the first sentence, "...flesh and about the same or slightly higher than poultry skin." The report also stated that daily increases in cholesterol consumption from use of MDP would be negligible on a per capita basis.

17. Page 16, paragraph 2: The 1978 regulation also required that MS(S) be listed in the ingredient statement. In 1982, the requirement that finished product names be qualified to indicate the presence of MS(S) was deleted.

18. Page 17, paragraph 2: Change "nitrates" to "nitrites."
(Paragraph 3)

19. Page 16: The first three words should be replaced by "compliance" and the footnote should be changed to read, "A standardized product is misbranded unless it conforms to the definition and standard. Economic adulteration may occur when valuable constituents are omitted or substances are substituted for them."

20. Page 25, footnote: Change "prearranged" to "unannounced, prescheduled."

21. Page 30, first recommendation: We suggest removing the specific example, since only cost considerations entered into the selection of that reduction. In reviewing verification sampling rates, FSIS will consider the impact on consumer protection--a perspective not undertaken by the report.

[GAO COMMENT: These comments have been incorporated where appropriate in the report.]

For sale by:

**Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20402**

Telephone (202) 783-3238

**Members of Congress; heads of Federal, State,
and local government agencies; members of the press;
and libraries can obtain GAO documents from:**

**U.S. General Accounting Office
Document Handling and Information
Services Facility
P.O. Box 6015
Gaithersburg, Md. 20760**

Telephone (202) 275-6241

